



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Arthrex, Inc.
David L. Rogers
Regulatory Affairs Associate
1370 Creekside Boulevard
Naples, Florida 34108-1945

January 16, 2015

Re: K143614

Trade/Device Name: Arthrex Low Profile Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, HRS
Dated: December 22, 2014
Received: December 23, 2014

Dear Mr. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.5 INDICATIONS FOR USE

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Indications for Use	Form Approved: OMB No. 0910-0120 Expiration Date: December 31, 2013 <i>See PRA Statement on last page.</i>
510(k) Number (<i>if known</i>) K143614	

Device Name

Arthrex Low Profile Screws

Indications for Use (*Describe*)

The Arthrex Low Profile Screws (2.0-3.0mm solid) are intended to be used as stand-alone bone screws, or in a plate screw system for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, and wrist. When used with a plate, the screw may be used with the Arthrex Low Profile and Small Fragment Plates.

The Arthrex Low Profile Screws (2.0-3.0mm cannulated) are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, and wrist.

The Arthrex Low Profile Screws (3.5mm and larger, solid) are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur, and fibula. When used with a plate, the screws may be used with the Arthrex Low Profile and Small Fragment Plates, Humeral Fracture Plates, and Osteotomy Plates.

The Arthrex Low Profile Screws (3.5mm and larger, cannulated) are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur, and fibula.

Type of Use (*Select one or both, as applicable*)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (*Signature*)

2.6 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Date Summary Prepared	October 8, 2014
Manufacturer/Distributor/Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	David L Rogers Regulatory Affairs Associate Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 71924 Fax: 239/598.5508 Email: david.rogers@Arthrex.com
Trade Name	Arthrex Low Profile Screws
Common Name	Screw, fixation, bone
Product Code -Classification Name	HWC – Screw, Fixation, Bone HRS – Plate, Fixation, Bone
CFR	21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Predicate Device	K103705: Arthrex Low Profile Screws
Purpose of Submission	This special 510(k) premarket notification is submitted to obtain FDA clearance for the use of Gamma Irradiation and Ethylene Oxide sterilization for the Arthrex Low Profile Screws which were cleared as non-sterile devices through K103705. This special 510(k) premarket notification is also intended to address the addition of 3.75mm Low Profile Screws and Low Profile Variable Angle Locking Screws as line extensions to the cleared predicate, which are similar in design and identical in material and intended use.
Device Description	The Arthrex Low Profile Screws are titanium or stainless steel, fully or partially threaded, solid or cannulated, self-tapping, headed screws. The screws range from 2.0mm to 4.0mm in diameter and in length from 8mm to 80mm.
Intended Use	The Arthrex Low Profile Screws (2.0-3.0mm solid) are intended to be used as stand-alone bone screws, or in a plate screw system for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, and wrist. When used with a plate, the screw may be used with the Arthrex Low Profile and Small Fragment Plates.

	<p>The Arthrex Low Profile Screws (2.0-3.0mm cannulated) are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, and wrist.</p> <p>The Arthrex Low Profile Screws (3.5mm and larger, solid) are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur, and fibula. When used with a plate, the screws may be used with the Arthrex Low Profile and Small Fragment Plates, Humeral Fracture Plates, and Osteotomy Plates.</p> <p>The Arthrex Low Profile Screws (3.5mm and larger, cannulated) are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur, and fibula.</p>
Substantial Equivalence Summary	<p>The Arthrex Low Profile Screws are substantially equivalent to the predicate devices in which the basic design features and intended uses are the same. Any differences between the Arthrex Low Profile Screws and the predicates are considered minor and do not raise questions concerning safety and effectiveness.</p> <p>The predicate screws are non-sterile. The proposed plates and screws will undergo Gamma Irradiation or Ethylene Oxide (EO) sterilization.</p> <p>The new 3.75mm Low Profile Screws and Low Profile Variable Angle Locking Screws are within the cleared size range of predicate K103705.</p> <p>Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex, Inc. has determined that the Arthrex Low Profile Screws are substantially equivalent to the predicates.</p>